REMARKS

Claims 1-76 are pending. Claims 1-76 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. Claims 54-75 stand rejected under 35 U.S.C. § 101 for being directed to non-statutory subject matter. Claims 1-11, 13-18, 20-27, 29-45, 48-50, 54-65, and 67-73 stand rejected under 35 U.S.C. § 102(e) for anticipation by Michaelis et al. (U.S. Patent Application Publication Number 2004/0034021; hereafter "Michaelis"). Claims 1-11 and 54-58 stand rejected under 35 U.S.C. § 103(a) for obviousness over Chamberland et al. (U.S. Patent No. 6,114,310; hereafter "Chamberland") in combination with Rose et al. (U.S. Patent No. 6,316,433; hereafter "Rose"). Claims 13, 34, 35, 37-53, 59, and 73-75 stand rejected under 35 U.S.C. § 103(a) for obviousness over Chamberland in combination with Rose and further in combination with Bostwick et al. (U.S. Patent No. 5,773,000; hereafter "Bostwick"). Claims 12, 14-33, 36, and 60-72 stand rejected under 35 U.S.C. § 103(a) for obviousness over Chamberland in combination with Rose and further in view of statements made in Applicant's specification. Each of these rejections is addressed below.

Applicant thanks Examiner Fubara for the interview conducted on May 2, 2006 and amends the claims along the lines discussed during the interview.

Support for each of the above amendments and new claims may be found throughout the specification and the claims. Support for the limitation in independent claims 1, 12, 35, and 48 that the rifalazil or compositions including rifalazil are optionally

formulated with one or more pharmaceutically acceptable excipients is found, for example, at page 8, lines 26-27 and page 10, lines 23-25 of the specification. Support for the limitation that the rifalazil is administered orally or rectally is found, for example, in original claim 11; at page 3, lines 3-4; page 14, lines 24-25; and in Example 1. Support for the combination of rifalazil and GT160-246 in claim 12 is found, for example, at page 3, lines 14-16. No new matter has been added by these amendments.

These amendments were made solely for the purpose of bringing this case to issuance, and Applicant reserves the right to pursue the subject matter canceled by this amendment in a continuing or divisional application. The claims, as amended, are consistent with the scope of subject matter believed to be deemed allowable by the Examiner.

Turning to the pending rejections, deletion of the limitation "preventing an infection of *Clostridium difficile*" from independent claims 1, 12, 35, and 48 obviates the rejection under 35 U.S.C. § 112, first paragraph. This rejection may be withdrawn.

The rejection under 35 U.S.C. § 101 is overcome by the cancellation of claims 54-75.

The rejection of claims 1-11, 13-18, 20-27, 29-45, 48-50, 54-65, and 67-73 under 35 U.S.C. § 102(e) for anticipation by Michaelis is overcome by the amendment of independent claims 1, 12, 35, and 48 to recite the limitation that the rifalazil is administered orally or rectally. As discussed during the Examiner interview, Michaelis

discloses rifalazil formulations for intravenous administration and does not describe methods for treating a subject having a *Clostridium difficile* infection that *consist of administering rifalazil orally or rectally.*

Independent claims 1, 12, 35, and 48 have been amended to recite the limitation that the methods *consist* of orally or rectally administering rifalazil (claim 1) or rifalazil in combination with GT160-246 (claims 12), one or more antibiotics (claim 35), or vancomycin (claim 48), optionally formulated with one or more pharmaceutically acceptable excipients. These claims are free of the prior art. All rejections under 35 U.S.C. § 103(a) are based on Chamberland as the primary reference, in combination with Rose, Rose and Bostwick, or Rose and Applicant's admissions in the specification. The methods and compositions taught by Chamberland require the combination of an antimicrobial agent with *an efflux pump inhibitor*. The amended claims are not rendered obvious by these Chamberland combinations because Chamberland does not teach or suggest methods limited to the use of rifalazil alone or rifalazil used in combination with GT160-246, one or more antibiotics, or vancomycin. Indeed, Chamberland teaches the critical importance of the use of an efflux pump inhibitor, a component excluded from Applicant's claims. The 35 U.S.C. § 103(a) rejection over Chamberland in view of Rose, Rose and Bostwick, and Rose and Applicant's admissions may be withdrawn.

CONCLUSION

Applicant submits that the claims are now in condition for allowance and such action is respectfully requested.

Applicant notes that the Form PTO 1449 that was submitted with an Information Disclosure Statement filed on September 22, 2005 has not been initialed and returned, and hereby request that it be initialed and returned with the next Office action.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 31 May 2006

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